

DRAFT

PM RESPONSE

RESPONSE TO DHHS/CDC MATERIALS ON ETS

"FACTS ABOUT SECONDHAND SMOKE"

General

CLAIM: "Secondhand smoke is a cause of disease, including lung cancer, in healthy nonsmokers. Each year secondhand smoke kills an estimated 3,000 adult nonsmokers from lung cancer."

RESPONSE:

- The claim of 3,000 deaths purportedly due to ETS exposure is derived from a risk assessment on ETS conducted by the U.S. Environmental Protection Agency. The risk assessment was based upon a statistical review, called "meta-analysis," of epidemiologic studies of nonsmoking women married to smokers.
- EPA reviewed 30 epidemiologic studies in the risk assessment. Of these, 24 reported no statistically significant overall risk estimate, meaning that those data are compatible with the hypothesis that there is no overall association between spousal smoking and lung cancer.

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- The meta-analysis conducted by EPA used 11 spousal smoking studies conducted in the United States. Not one of these studies originally reported a statistically significant overall risk estimate. Nevertheless, EPA used these studies to arrive at the conclusion that ETS exposure is associated with an increased risk of lung cancer.
- During the course of the development of the risk assessment, numerous critical scientific comments were provided to the Agency. For instance, more than 100 public comments were submitted on the first public draft of the risk assessment, in 1990. An EPA consultant involved in the risk assessment characterized the majority of the comments as "quite lengthy, detailed, and highly critical."
- Many of the points raised in the public comments in 1990, and in additional public comments provided to EPA in 1992, were not adequately addressed by the Agency before the risk assessment was finalized. For instance, a meta-analysis incorporating new United States studies was submitted to the Executive Committee of the EPA's Science Advisory Board; it yielded a summary risk estimate that was not statistically significant. Nevertheless, the

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risk assessment was finalized without taking into account these new data.

CLAIM: "Secondhand smoke causes 30 times as many lung cancer deaths as all regulated air pollutants combined."

RESPONSE:

- Claims of numbers of deaths purportedly due to ETS exposure are based on a process called risk assessment. In particular, the U.S. EPA has recently released a risk assessment on ETS, upon which CDC is presumably basing this claim.
- The estimates generated by risk assessments depend on the assumptions made in the risk assessment process. Comparisons of the results reported in different risk assessments, without regard to the assumptions and techniques used in each, is not appropriate.

CLAIM: "Secondhand smoke causes other respiratory problems in nonsmokers: coughing, phlegm, chest discomfort, and reduced lung function."

RESPONSE:

- Even the Surgeon General, in the 1986 report on ETS, concluded that the magnitude of the reported lung function

decrements in nonsmoking adults exposed to ETS were "quite small, even at moderate to high exposure levels" and that "it is unlikely that this change in airflow, per se, results in symptoms." (page 63)

- Regarding cough, phlegm and wheezing in adult nonsmokers, the Surgeon General reported that "few studies have addressed the relationship of chronic respiratory symptoms in nonsmoking adults with environmental tobacco smoke exposure." The Surgeon General reported on two studies (Schilling 1977; and Schenker 1982). Neither study reported an association between spousal smoking and an increased incidence of respiratory symptoms in nonsmoking women.
- The authors of the EPA risk assessment on ETS concede that the studies on ETS and adult respiratory health are "inconsistent and sometimes contradictory."
- Several literature reviews on ETS and adult respiratory health (not addressed in the EPA risk assessment) have contradicted the claim that ETS exposure is associated with respiratory symptoms in nonsmoking adults. For example, a review by Laurent, et al., (1990) suggested that the purported long-term health effects from exposure

to ETS are difficult to demonstrate in healthy adults and that the results of the epidemiological studies are "sometimes conflicting and often open to question." In a 1990 review, Witorsch noted that, in addition to "all of the problems" with the studies, "these results are too variable to permit any conclusion of association."

CLAIM: "For many people, secondhand smoke causes reddening, itching, and watering of the eyes. About eight out of 10 nonsmokers report they are annoyed by others' cigarette smoke."

RESPONSE:

- Persons may report "discomfort" or annoyance that they attribute to ETS. However, subjective perceptions are difficult to evaluate.
- Several studies with asthmatic individuals suggest that complaints of discomfort upon exposure to ETS may have a psychological component. For instance, ETS is recognizable by its appearance and odor. Moreover, recent published scientific research reports that visual contact with a smoker can affect persons' perceptions of the intensity of ETS odor.

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- The existence of allergens in tobacco smoke has not been established conclusively. Claims of annoyance and emotional responses should not be confused with genuine allergic reactions.
- A vast range of substances contribute to indoor air quality (IAQ). Singling out ETS for particular attention overlooks these other substances. Personal perceptions of comfort may be related to air temperature, relative humidity, lighting, and/or the presence of biological and chemical substances in the air.

CLAIM: "More than 4,000 chemical compounds have been identified in tobacco smoke. Of these, at least 43 are known to cause cancer in humans or animals."

RESPONSE:

- Animal inhalation experiments using fresh sidestream smoke or constituents of sidestream smoke do not support the claim that ETS causes cancer of the lung.
- Recent reviews of the literature on suspected pulmonary carcinogens have concluded that none of the individual constituents in sidestream smoke which are classified as potentially carcinogenic have been found to induce pulmonary cancer via inhalation in experimental animals.

- Positive results reported for skin painting, intratracheal implantation or subcutaneous application in animals are of questionable relevance to the mode of exposure (inhalation) for ETS.

CLAIM: "At high exposure levels, nicotine is a potent and potentially lethal poison. Secondhand smoke is the only source of nicotine in the air."

RESPONSE:

- Nicotine is subject to a threshold limit value (TLV) in workplaces. However, a recent review concluded that, given typical smoking rates and ventilation, "[i]t is unlikely for the nicotine level in public places to attain the TLV level."

CLAIM: "Nonsmokers exposed to cigarette smoke have in their body fluids significant amounts of nicotine, carbon monoxide, and other evidence of secondhand smoke."

RESPONSE:

- The scientific literature reports that nonsmokers who are exposed to realistic levels of ETS, when compared to nonsmokers who are not so exposed, exhibit no significant increases in body fluid levels of the various

- substances, e.g., mutagens, polycyclic aromatic hydrocarbons, hydroxyproline, and DNA adducts, proposed as biological markers for ETS exposure.
- While cotinine, a metabolite of nicotine, has been proposed as a biological marker to measure nonsmoker exposure to ETS, research indicates that there is not a direct correlation between exposure to nicotine in the ambient air and the existence of cotinine in body fluids. Differences in metabolism, diet and analytical method may all influence reported cotinine levels.

CLAIM: "Three out of four nonsmokers have lived with smokers, and nearly half (45 percent) are worried that secondhand smoke might cause them serious health problems."

RESPONSE:

- Such a claim is presumably based on results of a survey of some subgroup of the population. However, it is presented in a fashion that makes it appear to represent prevailing public opinion.

CLAIM: "More than 90 percent of Americans favor restricting or banning smoking in public places."

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RESPONSE:

- Such a claim is presumably based on results of a survey of some subgroup of the population. However, it is presented in a fashion that makes it appear to represent prevailing public opinion.

Children

CLAIM: Each year, exposure to secondhand smoke causes 150,000 to 300,000 lower respiratory tract infections (such as pneumonia and bronchitis) in U.S. infants and children younger than 18 months of age. These infections result in 7,500 to 15,000 hospitalizations yearly.

RESPONSE:

- These figures apparently were obtained from the EPA Risk Assessment on ETS.
- The EPA Risk Assessment does not appear to provide a statistical explanation for these estimations.
- A 1988 review of 30 of the major studies on parental smoking noted that while several studies of adequate scientific design reported an association between reported parental smoking and childhood respiratory conditions, "most studies had significant design problems that prevent reliance on their conclusions." The authors concluded

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that "many questions remain, and future studies should consider important methodological standards to determine more accurately the effect of passive smoking on child health." (Rubin & Damus, 1988)

CLAIM: Chronic cough, wheezing, and phlegm are more frequent in children whose parents smoke

RESPONSE:

The studies on childhood respiratory disease and parental smoking suffer from numerous methodological problems. Exposure to ETS is estimated by questionnaire responses from parents. Therefore, there is no quantitative data on the actual exposure levels of children in these studies. Also, important confounding variables are not consistently controlled for in the studies of parental smoking. Not surprisingly, the studies have reported conflicting and inconsistent findings.

CLAIM: Children exposed to secondhand smoke at home are more likely to have middle-ear disease and reduced lung function

RESPONSE:

- A 1992 review of the epidemiological literature reported that only six of the major 17 studies on middle ear disease and parental smoking reported a statistically significant association. (Hood et al., 1992)
- The reliability of lung function tests in the studies of parental smoking and children's lung function has been debated in the scientific literature. In 1982, a United States research group showed that a comparison of body size with lung function eliminated any reported correlation between parental smoking and children's lung function. The magnitude of pulmonary function changes reportedly associated with parental smoking is so small that researchers are unsure of any clinical significance of the reported decrements.
- After reviewing the literature on parental smoking and pulmonary function in children, researchers in 1992 asserted that the reported decrements in pulmonary function were, "with few exceptions," small and that all of the values were still within the normal range. (Hood et al., 1992)

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CLAIMS: Secondhand smoke increases the number of asthma attacks and the severity of asthma in about 20% of this country's 2 million to 5 million asthmatic children.

Each year, U.S. mothers who smoke at least 10 cigarettes a day can actually cause between 8,000 and 26,000 new cases of asthma among their children.

RESPONSES:

- The EPA Risk Assessment concedes that "the epidemiologic evidence is suggestive but not conclusive that ETS exposure increases the number of new cases of asthma in children who have not previously exhibited symptoms." (page 1-5) [emphasis added]
- Only five of 21 major studies on asthma in children and parental smoking have reported a statistically significant association. (Hood et al., 1992)
- The parental smoking studies on childhood asthma report inconsistent conclusions and suffer from several important methodological problems, such as inaccurate exposure assessment and confounding bias.
- The study that is used to support the claim that mothers who smoke 10 or more cigarettes a day may cause their children to develop asthma only reported the results for children of mothers with less than 12 years of

education. The authors reported that there was no association between maternal smoking and asthma in children with mothers who had more than 12 years of education. If there is truly a causal relationship between maternal smoking and asthma in children, then why should the relationship only exist in children of supposedly "less-educated" mothers? Obviously, other factors are at work here.

CLAIM: A recent study found that infants are three times more likely to die from sudden infant death syndrome (SIDS) if their mother smokes during and after pregnancy. Infants are twice as likely to die from SIDS if their mothers stop during pregnancy and then resume following birth.

RESPONES:

- The lead author of the NCHS study has been quoted as saying, "From this data, we have a fairly strong association but because of limitations of the data, we can't say there is a cause-and-effect relationship here."
(Kansas City Star, December 5, page A-9)
- The methods used to estimate exposure to tobacco smoke in this study are not accurate methods. The mothers filled out a survey of approximately 200 questions, an average of 19 months after the birth for case infants

and an average of 17 months after the birth for control infants. The question used to estimate exposure to parental smoking after birth was, "On the average, how many cigarettes do you smoke a day now?" The number of cigarettes a mother smokes as long as 18-19 months after the unexplained death of her infant is not necessarily the same as she smoked while the infant was still living. The authors themselves concede that their data "do not allow the determination" of such factors. The authors also concede that the accuracy of the self-reported data used to estimate exposure "is a concern."

- Apparently, the only major potential confounding variables considered in this study were maternal age, level of maternal education and marital status. There are many more potential confounding variables (such as sleeping position, type of feeding, etc.) which should have been considered.
- According to several research groups, although there are hundreds of published papers on SIDS, its cause or causes remain unknown. Even the authors of the present study concede that, "Although many theories have been proposed to explain the etiology of SIDS, an underlying cause for SIDS has not been identified."

- Researchers have questioned whether there is actually a condition known as SIDS or whether SIDS is actually a collective diagnosis assigned to many different types of unexplained infant deaths. The authors of the present study concede that, "As with any analysis of SIDS, this study is limited by the inherent difficulties in accurately identifying a death from SIDS."
- In the NCHS study, different relationships were reported for black and white infants between smoking by other household members and the risk of SIDS. Why would this be the case if there is a true relationship between amount of exposure to ETS and the risk of SIDS?

The authors of the study write:

To demonstrate a causal relationship between maternal smoking after pregnancy and SIDS death, it is necessary to determine that the mother spent a substantial amount of time with, and smoked cigarettes near, the infant. Unfortunately, the NMIHS lacks the detailed information necessary to make those determinations.

Workplace

CLAIM: "Workers exposed to secondhand smoke on the job are 34% more likely to get lung cancer."

RESPONSE:

- Claims that exposure to ETS in the workplace is associated with an increased risk of lung cancer are based on data reported in 14 "spousal smoking" studies that included an estimate of workplace exposure. Of the 18 published risk estimates for males and females, sixteen are not statistically significant. Moreover, the other two may be described as of only borderline statistical significance.
- Contrary to the position that there is a 34 percent excess risk associated with ETS exposure in the workplace, two recent meta-analyses of the available workplace data presented summary risk estimates that are statistically indistinguishable from 1.0, the baseline level of no increase in risk.
- Moreover, risk estimates of the magnitude such as those purportedly related to workplace ETS exposure may be categorized as "weak" in epidemiologic terms. Risk estimates of less than 2.0 or 3.0 are at the limit of detection of epidemiologic methods.

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CLAIM: "The simple separation of smokers from nonsmokers within the same airspace may reduce, but cannot eliminate, the exposure of nonsmokers to secondhand smoke."

RESPONSE:

- While some have claimed that simple separation of smokers and nonsmokers is not effective, numerous studies in the scientific literature report that simple separation effectively minimizes nonsmoker exposures to ETS.
- IAQ measurements taken under normal, everyday conditions indicate that the contribution of tobacco smoke to the ambient air is minimal.
- Typical nicotine measurements range from an exposure equivalent of 1/100 to 1/1000 of filter cigarette per hour. That means a nonsmoker would have to spend from 100 to 1000 hours in an office, restaurant or other public place in order to be exposed to the nicotine equivalent of a single cigarette.

CLAIM: "There is no safe level of exposure to a cancer-causing substance."

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RESPONSE:

- The concept of a "threshold" for possible carcinogens is a topic of scientific debate.

CLAIM: "Survey responses indicate that at least 4.5 million American workers experience great discomfort from exposure to secondhand smoke."

RESPONSE:

- The figure presented in this statement was presumably calculated by extrapolating from the reported results of a survey, and thus, depends on the population surveyed and the assumptions and margin of error of that survey.
- Persons may report "discomfort" or annoyance that they attribute to ETS. However, subjective perceptions are difficult to evaluate.
- Several studies with asthmatic individuals suggest that complaints of discomfort upon exposure to ETS may have a psychological component. For instance, ETS is recognizable by its appearance and odor. Moreover, recent published scientific research reports that visual contact with a smoker can affect persons' perceptions of the intensity of ETS odor.

- The existence of allergens in tobacco smoke has not been established conclusively. Claims of annoyance and emotional responses should not be confused with genuine allergic reactions.
- A vast range of substances contributes to indoor air quality (IAQ). Singling out ETS for particular attention overlooks these other substances. Personal perceptions of comfort may be related to air temperature, relative humidity, lighting, and/or the presence of biological and chemical entities in the air.

CLAIM: "The best method for controlling worker exposure to secondhand smoke is to eliminate tobacco use from the workplace and implement a smoking cessation program to support smokers who decide to quit."

RESPONSE:

- While some have claimed that simple separation of smokers and nonsmokers is not effective, numerous studies in the scientific literature report that simple separation effectively minimizes nonsmoker exposures to ETS.

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- IAQ measurements taken under normal, everyday conditions indicate that the contribution of tobacco smoke to the ambient air is minimal.
- Typical nicotine measurements range from an exposure equivalent of 1/100 to 1/1000 of filter cigarette per hour. That means a nonsmoker would have to spend from 100 to 1000 hours in an office, restaurant or other public place in order to be exposed to the nicotine equivalent of a single cigarette.

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"Secondhand Smoke in Your Home"

CLAIM: "Those most affected by secondhand smoke are children. Because their bodies are still developing, exposure to the poisons in secondhand smoke puts children in danger of severe respiratory diseases and can hinder the growth of their lungs. On top of that, the effects can last a lifetime."

RESPONSE:

- A 1988 review of 30 of the major studies on parental smoking noted that while several studies of adequate scientific design reported an association between reported parental smoking and childhood respiratory conditions, "most studies had significant design problems that prevent reliance on their conclusions." The authors concluded that "many questions remain, and future studies should consider important methodological standards to determine more accurately the effect of passive smoking on child health." (Rubin & Damus, 1988)
- The studies on childhood respiratory disease and parental smoking suffer from numerous methodological problems. Exposure to ETS is estimated by questionnaire responses from parents. Therefore, there are no quantitative data on the actual exposure levels of children in these studies. Also, important confounding variables are not

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consistently controlled for in the studies of parental smoking. Not surprisingly, the studies have reported conflicting and inconsistent findings.

- The reliability of lung function tests in the studies of parental smoking and children's lung function has been debated in the scientific literature. In 1982, a United States research group showed that a comparison of body size with lung function eliminated any reported correlation between parental smoking and children's lung function. The magnitude of pulmonary function changes reportedly associated with parental smoking is so small that researchers are unsure of any clinical significance of the reported decrements.
- After reviewing the literature on parental smoking and pulmonary function in children, researchers in 1992 asserted that the reported decrements in pulmonary function were, "with few exceptions," small and that all of the values were still within the normal range. (Hood et al., 1992)

CLAIM: "Even your pets will be happier. For example, secondhand smoke increases the risk of lung cancer in dogs."

RESPONSE:

- This claim is presumably based upon a single published "epidemiologic" study.
- In the study, the owners of 51 dogs diagnosed with lung cancer provided responses concerning smoking to a questionnaire.
- The reported overall point estimates of risk were not statistically significant.
- The authors of the study conceded that their reported findings were "weak" and "inconclusive."
- Moreover, the authors wrote that their study "suffers from some of the same limitations found in the studies done in humans," such as small sample size, problems in estimating exposure, and imprecise risk estimates.

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"Secondhand Smoke in the Workplace"

CLAIM: "In general, ventilation or filtration of air in the workplace to remove second hand smoke is futile. . . . The only viable approach to protect nonsmokers is source control."

RESPONSE:

- Numerous studies in the scientific literature report that simple separation of smokers and nonsmokers, even under conditions of recirculation, may reduce nonsmoker exposure to ETS constituents by as much as 90%.
- ETS constituent levels monitored in nonsmoking areas under restricted conditions are often below the level of detection for monitors of ETS constituents.
- Other published research indicates that ventilation at levels recommended by ASHRAE Standard 62-1989 is sufficient to maintain acceptable indoor air quality under conditions of "moderate" smoking.

CLAIM: "Every smoker costs his or her company at least \$1,000 a year because of decreased productivity and increased health care costs. Much of this money may be saved if a smoke-free policy is instated."

RESPONSE:

- Claims of cost savings related to smoking bans have not been substantiated in the literature.
- It is argued that smokers have higher rates of absenteeism than do nonsmokers. However, a number of factors involved with absenteeism (e.g., job responsibilities, job satisfaction, personal problems, family responsibilities, use of alcohol, etc.) have rarely been considered in the reported association.
- The claim that lower insurance premiums will result from a smoking ban also does not appear to be substantiated.
- Estimates of time lost on the job purportedly due to smoking are generally derived from interviews with employers who have instituted nonsmoking policies. The possibility of nonsmoker lack of productivity has not been considered in these polls.

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"Secondhand Smoke in Restaurants"

CLAIM: "Restaurants that allow smoking can have six times the pollution of a busy highway. Secondhand smoke has many of the same poisons as the air around toxic waste dumps."

RESPONSE:

- These claims have been chosen for their sensational appeal.
- The scientific literature includes a number of studies measuring indoor air quality in restaurants, bars and other public places. These studies indicate that nonsmoker exposure to ETS under normal, everyday conditions is minimal.
- For example, researchers report that there is little difference in ambient levels of carbon monoxide in smoking and nonsmoking areas of workplaces and public places and in homes with and without smokers.
- Other studies indicate that ETS contributes approximately 30 percent of the total particles in the air of a typical public place.

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- Typical measurements of nicotine range from an exposure equivalent of 1/100 to less than less than 1/1000 of one filter cigarette per hour. This means that a nonsmoker would have to spend from 100 to 1000 hours or more in an office, restaurant or public place in order to be exposed to the nicotine equivalent of a single cigarette.
- Studies which have examined ETS constituent levels of nitrosamines, nitrogen oxides and volatile organic compounds report minimal contributions to overall ambient air levels in homes, the workplace and public places.

CLAIM: "Ventilation systems are designed to efficiently circulate air within an enclosed environment, not to filter and clean it."

RESPONSE:

- Ventilation systems are designed not only to circulate air, but to introduce "fresh" outside air and to exhaust air from inside the structure.
- Scientific research indicates that ventilation at levels recommended by ASHRAE Standard 62-1989 is sufficient to maintain acceptable indoor air quality under conditions of "moderate" smoking.